

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {OUTER CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Domitor 1 mg/ml Solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml of solution contains:
Medetomidine hydrochloride 1 mg

3. PACKAGE SIZE

10 ml

4. TARGET SPECIES

Dogs and Cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For intravenous, intramuscular or subcutaneous injection

7. WITHDRAWAL PERIODS

Not applicable.

8. EXPIRY DATE

Exp. date:
Following withdrawal of first dose use within 3 months.
White Box: Once broached, use by:

9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Distributed by:

VETOQUINOL UK LIMITED
Pury Hill Business Park
Towcester
Northants
NN12 7LS

Marketing authorisation holder:

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Orion-logo
Vétoquinol-logo

14. MARKETING AUTHORISATION NUMBERS

Vm 06043/4003

15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING
UNITS {VIAL LABEL}**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Domitor 1 mg/ml solution for injection

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Medetomidine hydrochloride 1 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. date:

Following withdrawal of first dose use within 3 months.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

DOMITOR 1 mg/ml Solution for injection

2. Composition

A Clear, colourless aqueous solution for injection of medetomidine hydrochloride. Each ml contains medetomidine hydrochloride 1.0 mg.

Other ingredients: Methyl parahydroxybenzoate (E218) 1 mg/ml, Propyl parahydroxybenzoate 0.2 mg/ml.

3. Target species

Dogs and Cats.

4. Indications for use

1. Dogs:

For restraint, sedation and analgesia associated with clinical examinations and procedures, minor surgery and as premedication prior to general anesthesia. In combination with butorphanol for sedation and analgesia.

2. Cats:

For restraint and sedation.

In combination with ketamine for induction of general anesthesia prior to surgical procedures.

In combination with butorphanol for sedation and analgesia, and combined with both butorphanol and ketamine for general anesthesia.

As a premedication before alphaxalone/alphadolone for general anesthesia.

5. Contraindications

Do not use in animals with heart failure, respiratory disease or impaired liver or kidney function, animals in shock, seriously debilitated animals, or animals that are stressed due extreme heat, cold or fatigue. Do not use in conjunction with sympathomimetic amines.

Do not use in dogs under 12 weeks of age.

6. Special warnings

Special warnings:

A clinical examination should be carried out in all animals before the use of drugs for sedation and/or general anesthesia.

Care should be taken when using the veterinary medicinal product in animals with cardiovascular disease.

Care should be taken when combining medetomidine with other anaesthetics or sedatives. Before using any combinations consult the contraindications and warnings that appear on the concomitant product's data sheet.

Medetomidine has marked anaesthetic sparing effects. The dose of the anaesthetic should be reduced accordingly (see section Dosage and administration).

Special care is recommended when treating very young animals and older animals.

The veterinary medicinal product, ketamine and propofol are metabolised in the liver and excreted primarily via the kidneys. Pre-existing liver or kidney pathology should be carefully evaluated to confirm adequate function prior to using these products.

Fasting is recommended before Domitor administration. After treatment, the animal should not be given water or food before it is able to swallow properly.

Treated animals should be kept in a warm and even temperature during the procedure and for 12 hours after sedation.

During prolonged procedures an ophthalmic preparation should be administered at regular intervals to lubricate the cornea especially in cats and sometimes also in dogs if their eyes remain open.

In cats, when the veterinary medicinal product is used in combination with ketamine, laryngeal and pharyngeal reflexes are retained during anesthesia.

Special precautions for safe use in the target species:

When the veterinary medicinal product is administered, the animal should be allowed to rest in a maximally quiet place. Before any procedure is started or other drugs are administered, sedation should be allowed to reach its peak effect, which occurs at about 10 to 30 min, depending on route of administration.

In extremely nervous, excited or agitated animals, the levels of endogenous catecholamines may be high. The pharmacological response elicited by alpha-2 agonists (e.g. medetomidine) in such animals is often reduced, with depth and duration of sedative and analgesic effects ranging from slightly diminished to non-existent. Highly agitated animals should therefore be put at ease and allowed to rest quietly prior to receiving the veterinary medicinal product. Allowing animals to rest quietly for 10 to 15 minutes after injection may improve the response to the veterinary medicinal product.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In the case of accidental oral intake or self-injection, seek medical advice immediately and show the package leaflet to the doctor but DO NOT DRIVE as sedation and changes in blood pressure may occur. Avoid skin, eye or mucosal contact. Immediately after exposure, wash the exposed skin with large amounts of fresh water. Remove contaminated clothes that are in direct contact with skin. In the case of accidental contact of the product with eyes, rinse with large amounts of fresh water. If symptoms occur, seek the advice of a doctor. If pregnant women handle the product, special caution should be observed not to self-inject as uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.

Advice to doctors:

Medetomidine hydrochloride is an alpha-2 adrenoreceptor agonist. Symptoms after absorption may involve clinical effects including dose-dependent sedation, respiratory depression, bradycardia, hypotension, a dry mouth, and hyperglycaemia. Ventricular arrhythmias have also been reported. Respiratory and haemodynamic symptoms should be treated symptomatically.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

Interaction with other medicinal products and other forms of interaction:

Medetomidine should not be used in conjunction with sympathomimetic amines. The concomitant use of other central nervous system depressants should be expected to potentiate the effect of either product and appropriate dose adjustment should be made. Medetomidine must not be mixed with other products, with the exception of Vetalar and Ketaset Injection and Torbugesic injection.

Medetomidine has marked anaesthetic sparing effects. The dose of compounds such as propofol and volatile anaesthetics should be reduced accordingly, by up to 50 - 90%, depending on the individual animal.

Although bradycardia may be partially prevented by prior administration (at least 5 minutes before Domitor) of an anticholinergic agent, the administration of anticholinergic agents to treat bradycardia either simultaneously with medetomidine or following sedation with medetomidine could lead to adverse cardiovascular effects.

Overdose:

Overdose is mainly manifested by delayed recovery after sedation or anesthesia. In a few individuals, circulatory and respiratory depression may occur.

The effects of Domitor can be eliminated using the specific alpha-2 adrenergic antagonist atipamezole (Antisedan). In the dog, the Antisedan dosage expressed in mcg is 5 times that of Domitor. In the cat, the Antisedan dosage expressed in mcg is 2.5 times that of Domitor.

Special restrictions for use and special conditions for use:

Not applicable.

Major incompatibilities:

Medetomidine must not be mixed with other products with the exception of Vetalar and Ketaset injection and Torbugesic injection.

7. Adverse events

Dog

Very common (>1 animal / 10 animals treated):	Bradycardia ¹
Common (1 to 10 animals / 100 animals treated):	Vomiting ² Muscle tremor Decreased respiratory rate ³ Cyanosis
Undetermined frequency (cannot be estimated for the available data):	Excitation Heart block NOS ¹ Cardiac arrest ⁴ High blood pressure ⁵ Low blood pressure ⁵ Hypersensitivity reaction Hyperglycaemia Recovery prolonged ⁶ Sedation prolonged ⁷ Increased sensitivity to sound Urination ⁸ Apnoea ³ Hypoxia ⁹ Pulmonary oedema Death ¹⁰ Decreased body temperature Hypothermia ⁶ Lack of efficacy – NOS

¹Bradycardia with occasional atrioventricular block may occur.

²Some dogs vomit 5 to 15 minutes after injection.

³Decreased respiratory rates with or without transient apnoea periods may occur.

⁴ If the animal has a pre-existing subclinical respiratory disease, administration of the veterinary medicinal product can cause significant respiratory depression which could predispose to cardiac arrest.

⁵Blood pressure will increase initially and then return to normal or slightly below normal.

⁶Prolonged recovery may lead to hypothermia.

⁷Recurrence of sedation after initial recovery has also been reported.

⁸Urination typically occurs during recovery at about 90 to 120 minutes post-treatment.

⁹In some cases at higher dosages, a decline in arterial oxygen tension may occur.

¹⁰Death from circulatory failure with severe congestion of the lungs, liver, or kidney has been reported.

When the veterinary medicinal product is used in combination with propofol, movement of the forelegs may occur during induction of anaesthesia.

Cat

Common (1 to 10 animals / 100 animals treated):	Vomiting ¹
Undetermined frequency (cannot be estimated for the available data):	<p>Excitation</p> <p>Bradycardia²</p> <p>Heart block NOS²</p> <p>Cardiac arrest³</p> <p>High blood pressure⁴</p> <p>Low blood pressure⁴</p> <p>Hypersensitivity reaction</p> <p>Hyperglycaemia</p> <p>Recovery prolonged⁵</p> <p>Sedation prolonged⁶</p> <p>Muscle tremor</p> <p>Increased sensitivity to sound</p> <p>Urination⁷</p> <p>Apnoea⁸</p> <p>Decreased respiratory rate^{8,9}</p> <p>Pulmonary oedema</p> <p>Death¹⁰</p> <p>Cyanosis</p> <p>Decreased body temperature</p> <p>Hypothermia⁵</p> <p>Lack of efficacy – NOS</p>

¹Most cats vomit 5 to 15 minutes after injection, some cats may also vomit upon recovery.

²Bradycardia with occasional atrioventricular block may occur.

³If the animal has a pre-existing subclinical respiratory disease, administration of the veterinary medicinal product can cause significant respiratory depression which could predispose to cardiac arrest.

⁴Blood pressure will increase initially and then return to normal or slightly below normal.

⁵Prolonged recovery may lead to hypothermia.

⁶Recurrence of sedation after initial recovery has also been reported.

⁷Urination typically occurs during recovery at about 90 to 120 minutes post-treatment.

⁸Decreased respiratory rates with or without transient apnoea periods may occur.

⁹In some cats very slow respiratory rates are observed (4-6 breaths per minute).

¹⁰Death from circulatory failure with severe congestion of the lungs, liver, or kidney has been reported. When the veterinary medicinal product is used in combination with ketamine, the combination is reported to elicit a pain response in some cats when administered intramuscularly.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes. Administration by intramuscular (IM), intravenous (IV) and subcutaneous (SC) routes are possible. The effect is most rapid after IV administration and slowest after SC administration. The dosage is dependent on the degree of sedation and analgesia required.

Domitor	Dose mcg/kg
Dogs	10-80
Cats	50-150

For sedation, small dogs require more Domitor per kg of bodyweight than large dogs thus the dosage per square meter of body surface could be more accurate. If this

approach is used the dosage is 750 to 1000 mcg/square meter. The following table gives the dosage for dogs on the basis of body weight.

Body weight (kg) IV administration	Injection volume (ml)	Body weight (kg) IM/ SC/ administration
1.5-2.2	0.1	
2.3-3.5	0.15	1.8-2.3
3.6-5.1	0.2	2.4-3.3
5.2-6.9	0.25	3.4-4.5
7.0-9.9	0.3	4.6-6.4
10.0-14.4	0.4	6.5-9.4
14.5-19.5	0.5	9.5-12.7
19.6-25.1	0.6	12.8-16.3
25.2-31.1	0.7	16.4-20.2
31.2-37.6	0.8	20.3-24.4
37.7-44.4	0.9	24.5-28.9
44.5-55.3	1.0	29.0-36.1
55.4-71.1	1.2	36.2-46.3
71.2-88.2	1.4	46.4-57.3
88.3 +	1.6	57.4-75.8
	2.0	75.9 +

Anesthesia:

Domitor is suitable for use as an anesthetic premedication prior to general anesthesia. **Premedication dosing guide:** Medetomidine has marked anaesthetic-sparing effects. It is essential to reduce appropriately the dose of anaesthetic induction and maintenance agents in animals that have been given the product.

Combinant	Dosage (Dogs)		Dosage (Cats)	
	Domitor (mcg/kg)	Combinant (mg/kg)	Domitor (mcg/kg)	Combinant (mg/kg)
Propofol	10-40	1-4	NA	NA
Butorphanol	10-25	0.1	50	0.4
Ketamine			80	2.5-7.5
Butorphanol + Ketamine	NA	NA	40-80	But: 0.1-0.4 Ket: 1.25-5.0
Alfaxalone /alfadolone	NA	NA	80	2.5-5.0

9. Advice on correct administration

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not freeze.

Discard unused material.

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf-life after first opening the immediate packaging: 3 months.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription

14. MARKETING AUTHORISATION NUMBER AND PACK SIZES

Vm 06043/4003

10 ml vials.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

Orion Corporation

Orionintie 1

FI-02200 Espoo

Finland

Local representatives and contact details to report suspected adverse reactions:

VETOQUINOL UK LIMITED

Steadings Barn

Pury Hill Business Park

Nr Alderton

Towcester

Northants

NN12 7LS

Tel: +44(0)1280 814 500

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder

17. Other information

POM-V

Gavin Hall
Approved: 08 April 2026